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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,310	01/21/2000	Gary Stephenson	7922	5677

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER

ROSE, SHEP K

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/489310

Applicant(s)
STEPHENSON

Examiner
SKB/ROB

Group Art Unit
1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on Feb 13 2002
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 115 1720 2231 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 115 1720 2231 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Applicant's February 13, 2002 response never received, and was faxed on July 3, 2002, at the suggestion of the Examiner, entered July 25, 2002 and is available to be considered herein.

Original method of treating dental erosion claims 1 to 10 had been cancelled and are now represented as method claims 23 to 31, the only difference from the cited prior art acidic beverages, free of calcium and fluoride, pH 2 or 2.7 to 3.5 or 4.5, with sodium hexametaphosphate, encompassed by the structure formulae claimed, as enabled herein, is the statement of intended use "to treat dental erosion" but there is no claim required that the "mammal", to which it is orally administered, -- has dental erosion - - and / or - - is in need thereof - -. There is no novelty over each of the sodium hexametaphosphate added acidic pH fruit Juice beverages described by each of: Calderas, Montezinos (I-II), E kanayake et al, Mc Kenna et al, Tung et al, Ciragliano et al (I-II), Sokolik et al or Zablocki et al, (pertinency: oral ingestion inherently described) on pages 7, 9, 10 of the November 27, 2001 Office Action, and no remarks otherwise.

Applicant's counsel's remarks argues technical facts, on page 3, (denying) lines 3 to 5 "that the elected sodium hexametaphosphate will (expectedly) yield (polyp phosphate ion in water", on page 6, lines 9 to 11 that the presently recited polyphosphate compounds would be usefule as a substitute for the monosodium dihydrogen phosphate of Muhler and McDonald et al for their purpose of treating dental erosion. Applicant's counsel draws technical fact distinctions between the laboratory rat's, diet (feed) and between reducing dental caries not dental erosion, arguing that providing efficacy against dental erosion in the acidic environment of acidic beverages

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having a pH of less than 5 "would have been unexpected", that dental caries is the result of the direct action of bacteria on the enamel, where as erosion is rather related to the direct action of acid". This argument seems to ignore the technical fact that the bacteria produce the acid that causes the dental caries; the acid erodes the dental enamel.

Counsel's remarks have been considered, but are not seen as a substitute for a Rule 132 Declaration of an expert, when technical facts are being argued by counsel. Attorney argument is not evidence, unless it is an admission. See: In re De Blauwe, 222 USPQ 191, 196; Meitzner v. Mindick, 193 USPQ 17, 22, In re Pearson, 181 USPQ 641, 646, In re Lindner, 173 USPQ 356, 358; In re Schalze, 145 USPQ 716, 718; In re Cole, 140 USPQ 230, 233, and In re Walters, 77 USPQ 609, 610.

For clarity of prosecution, the following is noted about printed matter a necessary component of the claimed "KIT".

The printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture.

See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned... in accordance with the patent statutes, an article or composition of

matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC) USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The KIT'S claimed articles remain fully functional absent the labeling or printed instructions for use.

It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 2111.03:

Thus the instructions for use included in, or labeled on, a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03:

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Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967);

In the instant case, the "KIT" claims are drawn to an old composition article of manufacture which further comprises labeling instructions. The intended use which is recited on the label or package of the KIT insert lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, it can still be used by the skilled artisan for other purposes. Therefore the old article or old composition of the KIT, the old article or composition which are comprised within the claimed "KIT" article of manufacture are unpatentable over the prior art, because they function equally effectively with or without the labeling and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition a "KIT" and a package insert, with or without media messaging the instructions on the insert bearing no patentable weight with regard to double patenting, 102, and 103 rejections.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23 to 31 are rejected under 35 U.S.C. 102(b) as being anticipated by each of:

Calderas (sodium hexametaphosphate, same as herein), Smith et al., Montezinos (I-II), Ekanayake et al. (same), McKenna et al., Tung et al., Cirigliano et al. (I-II), Sokolik et al., and Zablocki et al. each not admittedly describing encompassed species of acidic beverages having a pH less than about 5, not admittedly containing sodium hexametaphosphate, (same as elected herein), or other encompassed species of sodium or potassium, condensed phosphate or polyphosphate salts, Calderas, for example employing 900 to 3000 parts per million polyphosphate with sodium hexametaphosphate, same as applicant herein in Examples 1-4), as the encompassed polyphosphate, in a non-carbonated acidic beverage having a pH of between 2.5 and 4.5, as see column 4 lines 7-32 in fruit juices at column 7 lines 39-68, as elected and tea at column 8 lines 12-28, with encompassed species of sweeteners at column 8 lines 30-68, (also avoiding calcium as well as iron and magnesium fortification since these polyvalent cations combine to and inactivate the polyphosphate component of the non-carbonated beverages, as see column 9 lines 27-30,) and only differing from these methods of orally ingesting acidic beverage with sodium hexameta (or other polyphosphate) claims in not providing information that use of the sodium hexametaphosphated acidic beverage provides the inherent dental erosion advantage, benefit, or property.

Smith et al. (Proctor & Gamble), similar to Calderas (Proctor & Gamble), include 300 ppm to 3000 ppm of an encompassed polyphosphate having an average chain length of about 17 to about 60, an encompassed species of a non-carbonated beverage having a pH of between 2.5 and 4.5, differing from these methods claims in not providing the inherent dental erosion treatment advantage or benefit information feature, from the oral ingestion of the same acidic beverage with the same sodium hexametaphosphate.

The prior art polyphosphate supplemented acid beverages are inherently orally ingested, they do not become patentable as "new use" methods for treating dental erosion, even by being marketed in the medin and/or labeled with associated information to the effect that since polyphosphates may prevent tooth erosion, or caries, (as see Harris et al (1967) McGaughey et al (1977) and Shibata et al. (1982)), that they may thereby reduce the tooth erosion potential of the acid low pH beverages, an expected property described for them by Lussi et al., (1995).

Respectively, it being not admitted prior art only that fluoride and/or calcium but not polyphosphates can expectedly lessen dental erosion, the improvement to such dental eroding ingestible acid low pH beverages free of calcium and fluoride being the inherent advantage, benefit or property of reducing tooth erosion, and that "information" is provided with the beverage that it contains sodium or potassium polyphosphate salts "treats dental erosion". These method claims are to a "new use" of a known beverage, another reason to market it, and consumers to drink it. Is this patentable? As method claims 23 to 31? Are they novel?

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Claims 1 to 10, all method claims were previously canceled and have been represented as claims 23 to 31, claims 11 to 15, 17 to 20, and 22 to "KITS" remain presented as the balance of the claims previously amended to have the acidic polyphosphate beverage substantially free of calcium and fluoride.

A telephone interview October 18 as a follow-up of the earlier interview Friday May 25, 2001 between the undersigned USPTO Examiner and applicants' counsel, Kelly McDaw-Dunham, clarified the page 8 election, with traverse, of one ultimate disclosed species of (B) beverages containing fruit juice and (c) carbohydrate sweeteners, since both are generic to plural species. All fruit juice species and all carbohydrate sweeteners are considered to be obvious variants of each other, and, accordingly, are not to be regarded as patentably distinct species.

The election, without traverse, was of: a "KIT" with "information" of:

(A) sodium hexametaphosphate, n=21; (as in Examples 3 and 4); the elected polyphosphate

(B) beverages containing fruit juice; (as in Examples 3 and 4); the elected acidic beverage

(C) carbohydrate sweeteners, as high fructose corn syrup (Example 3) , or sugar (Example 4); (known to cause "caries");

(D) substantially free of calcium and fluoride, (both known to reduce tooth erosion in acidic beverages) as required by the claims as presently amended.

The Examiner regards claim-encompassed polyphosphates and elected sodium hexametaphosphate (n=21) as well-known commercially available source anticaries

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compounds to inherently yield phosphate ion in water, and the tooth erosion benefit of the sodium phosphate salt monosodium dihydrogen phosphate, "MDP", NaH_2PO_4 discovered by McDonald et al and Muhler to reduce tooth erosion in such acidic beverages, to be due to the expected release of phosphate ion upon aqueous dissolution of the phosphate salt. Applicant's counsel's remarks a tribute to the examiner a release of polyphosphate ion; the Office Action expressly states phosphate ion is released in water by sodium hexametaphosphate

Whether or not the selection of sodium hexametaphosphate polyphosphate would be immediately envisioned for the same tooth erosion benefit, expected from phosphate ion or whether or not one skilled in the art would have motivation to substitute sodium hexametaphosphate or other encompassed species of polyphosphates for the tooth erosion benefiting phosphate ion from monosodium dihydrogen phosphate, based on expert knowledge that both are well known sources of phosphate ion (not polyphosphate ion as argued) requires a Rule 132 Declaration of an expert (i.e. by applicants or colleagues). Counsel's remarks are respected but are not considered herein to be an expert's opinion.

The prior art polyphosphate supplemented acid beverages do not become patentable "KITS" by being labeled with associated information to the effect that since polyphosphates may prevent tooth erosion, or caries, (as see Harris et al (1967) McGaughey et al (1977) and Shibata et al. (1982)), that they may thereby reduce their tooth erosion potential of the acid low pH beverages, an expected property described for them by Lussi et al., (1995).

Thus the claims are addressed as being drawn to an article of manufacture comprising and old composition "KIT" with a package insert, the instructions on the insert bearing no patentable weight.

The novelty of kit claims 11 to 15, 17 to 20 and 22, over inadvertently overlooked not admitted above note cited and applied prior art acidic beverages containing the sodium or potassium species of encompassed polyphosphates (included described or taught for reasons other than to treat dental erosion) (cited as known on the PTO-892 attached), (clearly meeting Part (a) of claim 1), is found in Part (b) of "KIT", "INFORMATION THAT THE USE OF THE BEVERAGE COMPOSITION PROVIDING TREATMENT AGAINST DENTAL EROSION". The CCPA in 1947 in In re Haller, 73 USPQ 403, held that novelty cannot be predicated on printed instructions (or on a label to reconstitute or to dilute a known composition with water to use it as an insecticidal spray). This Court case never overturned is binding as a precedent and Federal Circuit precedents are binding on USPTO examiners. The Miller and Gulack decisions can be distinguished on their facts, they involve functional elements claimed in Miller, a ratio indicating legend and volumetric indicia on a measuring receptacle in Gulack the printed material was novel and non-obvious both cases are prior to the recent Atlas case.

Claims 11 to 15, 17 to 20 and 22 to "KITS" stand rejected under 35 U.S.C. 103(a) as being unpatentable over the foregoing sodium hexametaphosphate added acidic pH fruit juice beverages described by each of the foregoing: Calderas, or Smith et al, (details as noted above) none of which describe the information component or even the reduction of tooth erosion benefit imparted to the acidic pH fruit juice benefit by virtue of the sodium hexametaphosphate, taken in further view of anyone of each of Shibata et al

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(1982) or McGaughey et al (1977) or Harris et al (1967) and one of each of Muhler (1970) (as abstracted) and McDonald et al. (1973) (Details as noted above), each anticipating the addition of a sodium or potassium phosphate salts source of phosphate ion to such a low pH acid beverage.

To reduce their tooth eroding potential with such potassium polyphosphates or condensed phosphate salts, as sources of phosphate ion as well as the selection of these encompassed low pH acid fruit juice beverage species, to practice this would be prima facie obvious as apt sources for phosphate ion, if not immediately envisioned, In re Schaumann et al ., 197 USPQ 5. The feature of kit claims of including information that the use of the beverage provides treatment against dental erosion is not patentable thereover, (In re Haller, 73 USPQ 403, CCPA-1947) since it is predicated on printed matter on or "associated with" (advertising in the media) the otherwise old beverage or its package.

Claims 11 to 15, 17 to 20, 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of each of: Shibata et al (1982); MC Gaughey et al (1977) or Harris et al (1967) each teaching the anticaries advantage benefit or property of sodium hexametaphosphate (as elected) and the other claim encompassed polyphosphate species, taken with anyone of each of: Lussi et al (1995); Ruessner et al (1975); McDonald et al (1973); or Muhler (1970), each describing the tendency of such acidic and sugar sweetened beverages, having a pH of less than about 5, "substantially free" of calcium and fluoride, to cause caries, i.e. to cause dental erosion. The primary references (Shibata et al, McGaughey et al, and Harris et al) clearly motivate the

inclusion of anticaries tooth protective amounts of sodium hexametaphosphate and analogous encompassed species of polyphosphate into such tooth eroding acidic beverages, as described by Lussietal, Russner et al, McDonald et al, and Muhler, and whose sugar sweetener can also cause caries. It is obvious to market the combination with media and label information, provided to inform the user of a reduced cariogenic tendency to cause dental erosion, as claimed in these "KITS"..

Lussi et al. (1995) (as noted above) identifying the species of low pH tooth erosive acid beverages encompassed by these claims to include orange juice and other citrus and fruit juices, apple juice, Sprite, Coca cola, Lemon Lime and other carbonated soft drinks, Sweppes, sports drinks, wine and beer, to some of which fluoride had been added to minimize (but not totally prevent) tooth erosion, differing from these "KITS" in having no polyphosphate content and no "information" component.

Ruessner et al (1975), describe and anticipate the addition, to encompass species of acidic beverages, namely encompassed pH range canned and frozen orange juice, and carbonated lemon lime beverages, of encompassed percentages of phosphates, namely (page 366, column 1, Table I), 0.15% sodium trimetaphosphate; an encompassed polyphosphate species 0.21% monosodium orthophosphate (NaH_2PO_4); with or without 0.08% monofluorophosphate, or 0.15% calcium chloride, the levels of the phosphate compound selected to yield 0.5 mg of phosphorus per ml, and 0.5 mg per ml of calcium. It is presumed that the researchers, being literate, provided labels, with information, to guide the trials. A control group had no calcium or polyphosphates in encompassed concentrations, with and without sucrose and/or glucose, as providing

anti-carries activity, as tested at 2% phosphate level and high sugar diet (in hamsters) in the absence of fluoride, in Shibata et al. It is presumed that the hamsters (users) could not read or understand any labeled information provided, but that the literate researchers labeled the experimental acidic juices and acidic soda beverages or meeting these "KIT" claims information part B.

Examiner cited Muhler (1970) South Africa 6904743, and McDonald et al. (1973), both cited on the PTO-892 teach and describe the feature of adding a sodium phosphate salt-monosodium dihydrogen phosphate to impart phosphate ion s to acid pH beverages to reduce tooth erosion, same as herein. The feature of selecting polyphosphates as phosphate ion sources remains prima facie obvious, if not in fact "immediately envisioned" species under In re Schaumann et al ., 197 USPQ 5, with no Rule 132 expert declaration evidence to the contrary.

Shibata et al. (1982), McGaughey et al. (1977) and Harris et al (1967) all, (cited by applicant) each motivates the inclusion in the diet or drinking water beverage of encompassed species of these anticaries condensed phosphates of polyphosphates, but are silent on any "information" provided to guide the researchers.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. The Examiner has

responded to counsel's remarks and has changed each occurrence of "admitted prior art" to "not admitted prior art".

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Rose/LR
August 15, 2002



SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200